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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,740	09/29/2003	Wei Liu	01997.022600	8198

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EXAMINER	
PHAM, AUDREY S	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 11/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/671,740	LIU ET AL.	
	Examiner	Art Unit	
	Audrey S. Pham	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-25 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-25 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Re: Liu, *et al.*

Claims 1-25 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-2, drawn to a method of diagnosing kidney cancer in a mammalian patient comprising detecting the amount of CD70 that is present in the patient sample, and comparing the amount of CD70 in the patient sample as against the amount of CD70, classified in class 435, subclass 335.

II. Claims 3-4, drawn to a method of diagnosing kidney cancer in a mammalian patient comprising detecting the amount of CD203c that is present in the patient sample, and comparing the amount of CD203c in the patient sample as against the amount of CD203c, classified in class 435, subclass 4.

III. Claim 5, drawn to an assay to detect the presence of renal cell carcinoma cells or clear cell renal cell carcinoma cells in a human patient comprising taking a kidney tissue sample or blood sample from the patient, detecting the amount of CD70 and CD203c in the patient sample and comparing the amount of CD70 and CD203c, classified in class 435, subclass 325.

IV. Claims 6-9, drawn to a pharmaceutical composition comprising a hybrid molecular structure, comprising a molecule that specifically targets CD70 linked to a cellular killing agent, and a pharmaceutically acceptable carrier wherein the composition destroys malignant kidney tissue, classified in class 530, subclass 350.

V. Claims 10-13, drawn to a pharmaceutical composition comprising a hybrid molecular structure, comprising a molecule that specifically targets CD203c linked to a cellular killing agent, and a pharmaceutically acceptable carrier wherein the composition destroys malignant kidney tissue classified in class 530, subclass 350.

VI. Claims 14-20, drawn to a method of treating a human patient that has or at risk of developing renal cell carcinoma or clear renal cell carcinoma comprising preparing an immunoconjugate comprising a cellular killing agent linked to a monoclonal antibody directed against CD70 and administering the immunoconjugate to the patient in a pharmaceutically effective dose, classified in class 424, subclass 145.1

VII. Claims 14-20, drawn to a method of treating a human patient that has or is at risk of developing renal cell carcinoma or clear renal cell carcinoma comprising preparing an immunoconjugate comprising a cellular killing agent linked to a monoclonal antibody directed against CD203c and administering the immunoconjugate to the patient in a pharmaceutically effective dose, classified in class 424, subclass 130.1.

VIII. Claims 20, drawn to a method of treating a human patient that has or is at risk of developing renal cell carcinoma or clear cell renal cell carcinoma comprising administering a peptide fragment that exhibits affinity for CD70, classified in class 424, subclass 141.1.

IX. Claims 20, drawn to a method of treating a human patient that has or is at risk of developing renal cell carcinoma or clear cell renal cell carcinoma comprising administering a peptide fragment that exhibits affinity for CD203c, classified in class 424, subclass 184.1.

X. Claims 20, drawn to a method of treating a human patient that has or is at risk of developing renal cell carcinoma or clear cell renal cell carcinoma

comprising administering a synthetic composition that exhibits affinity for CD70, classified in class 424, subclass 9.1.

XI. Claims 20, drawn to a method of treating a human patient that has or is at risk of developing renal cell carcinoma or clear cell renal cell carcinoma comprising administering a synthetic composition that exhibits affinity for CD203c, classified in class 424, subclass 9.34.

XII. Claims 21-25, drawn to a method of reducing or stopping the growth of malignant kidney tissue in a mammalian patient comprising reducing the level of CD70 by using an RNA interference strategy, classified in class 514, subclass 44.

XIII. Claims 21-25, drawn to a method of reducing or stopping the growth of malignant kidney tissue in a mammalian patient comprising reducing the level of CD203c by using an RNA interference strategy, classified in class 514, subclass 44.

The inventions are distinct, each from the other for the following reasons:

The inventions of groups IV-V and the methods of groups I-III, VI-XIII are related as products and processes of use. The inventions can be shown to be distinct if one of the following can be shown: (i) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § 806.05(h)]. In the instant case, the pharmaceutical composition comprising a hybrid molecular structure, as claimed in the inventions represented by groups IV-V, can be used in a materially different process such as in methods of treating cancer, methods of diagnosing cancer, methods of making a vaccine or methods of making said hybrid molecular structure.

The inventions of groups IV-V encompass distinct and independent products that encompass different functional as well as structural formulas. Group IV encompasses a

pharmaceutical composition comprising a molecule that specifically targets CD70 linked to a cellular killing agent. Conversely, group V encompasses a pharmaceutical composition comprising a molecule that specifically targets CD203c linked to a cellular killing agent. CD70, a cytokine, is disclosed to be distinct from CD203c, a nucleotide pyrophosphatase/phosphodiesterase 3, phosphodiesteraseI/nucleotide pyrophosphatate 3 (spec pages 1 & 4). Each of these groups represents a separate and distinct chemical product that is made by a materially different method, and is used in materially different method, which has a different mode of operation, different function and different effect. Conducting searches of both inventions would impose a serious burden because a search for one group would not be used to determine the patentability another group and vice-versa. Therefore, the two pharmaceutical compositions are patentably distinct.

The inventions of groups I-III, VI-XIII are materially distinct methods, which differ at least in objectives, method steps and reagents. Specifically, the inventions of groups I-II are drawn to methods of diagnosing kidney cancer, group III is drawn to an assay to detect the presence of CD70 and CD203c, groups VI-XI are drawn to treating a human patient and groups XII-XIII are drawn to methods of reducing the growth of malignant kidney tissue comprising using an RNA interference strategy. Each group uses different method steps and reagent to accomplish the various objectives or even the same objective. For example, groups VI-XI are drawn to methods of treating a human patient that has or at risk of developing renal cell carcinoma or clear cell carcinoma, however, each method uses different steps and reagents to achieve treatment. Group VI comprises an immunoconjugate comprising a cellular killing agent linked to a monoclonal antibody directed against CD70. Group VII comprises an immunoconjugate comprising a cellular killing agent linked to a monoclonal antibody directed against CD203c. Group VIII comprises administering a peptide that exhibits affinity for CD70. Group IX comprises administering a peptide that exhibits affinity for CD203c. Group X comprises administering a synthetic composition that exhibits affinity for CD 70 and Group XI comprises administering a synthetic composition that exhibits affinity for CD203c. Searching all of the groups with all of the different reagents, steps or objectives would invoke a serious burden of search.

These inventions are distinct for the reasons given above and they have acquired separate statuses in the art as shown by their different classifications. The search required for one group is not required for the other groups and vice versa. For these reasons, restriction for examination purposes as indicated is proper.

Species Election

One or more of the inventions above contain multiple generic claims that include a plurality of alternatively usable substances or members. These alternative limitations are independent or distinct inventions such that they do not share a common utility or share a substantial structural feature disclosed as being essential to that utility. Because they are not so closely related, a search and examination of the entire claim cannot be made without undue burden. The members of the alternative groupings are described in the following:

Groups III, V, VI (Claims 8, 15-16, 18-19) are generic to a plurality of disclosed patentably distinct species comprising the following cellular killing agents: cytotoxic agent, radioactive agent, calicheamicin, and a calicheamicin derivative.

The products of the above species represent separate and distinct agents with different structures and functions such that one species could not be interchanged with the other. As such, each species would require different searches and the consideration of different patentability issues.

Upon election of group III, V or VI, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims

readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Rejoining Claims

NOTE:

The Examiner has required restriction between product and process claims. Where Applicant elects claim(s) directed to a product and the product claim(s) is/are subsequently found allowable, the withdrawn process claim(s) that depend(s) from or otherwise include all the limitations of the allowable product claim(s) will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if an amendment is presented prior to a final rejection or allowance, whichever is earlier. Amendment submitted after final rejection is governed by 37 CFR 1.116; amendment submitted after allowance is governed by 37 CFR 1.312.

In the event of a rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claim(s) and process claim(s) may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the withdrawn process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Inventorship Amendment

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended to be in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request, as set forth in 37 CFR 1.48(b), and by a processing fee, as set forth in 37 CFR 1.17(i).

Contact Information

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Audrey S. Pham whose telephone number is (571) 272-3323. The Examiner can normally be reached during the hours of 8:30 AM - 5:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Jeffrey Siew, can be reached during business hours at the telephone number: (571) 272-0787. The fax number for the organization, where this application or proceeding is assigned, is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Audrey S. Pham
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GARY B. NICKOL, PH.D.
PRIMARY EXAMINER